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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,046	02/03/2004	Brian Hague	CP246	2324

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EXAMINER	
VANIK, DAVID L	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,046	HAGUE ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-104* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Applicant's Information Disclosure Statements filed on 9/2/2004 and 9/13/2004.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-42, drawn to a composition comprising (1) an ionizable pharmaceutical agent, (2) a buffer, (3) a pharmaceutically acceptable excipient, and (4) wherein the composition is substantially sugar-free, classified in class 424, subclass 440.

   II. Claim 44-95, drawn to a composition comprising (1) fentanyl or a pharmaceutically acceptable salt thereof, (2) a pharmaceutically acceptable excipient, and (3) wherein the composition is substantially sugar-free, classified in class 424, subclass 439.

   III. Claim 96, drawn to a method for the oral transmucosal delivery of a composition comprising (1) an ionizable pharmaceutical agent, (2) a buffer, (3) a pharmaceutically acceptable excipient, and (4) wherein the composition is substantially sugar-free comprising, classified in class 424, subclass 434.

   IV. Claim 97, drawn to a method for the oral transmucosal delivery of a composition comprising (1) fentanyl or a pharmaceutically acceptable salt thereof, (2) a pharmaceutically acceptable excipient, and (3) wherein the

composition is substantially sugar-free, classified in class 424, subclass 434.

V. Claims 98-101, drawn to a method of treating pain comprising introducing a composition comprising (1) an ionizable pharmaceutical agent, (2) a buffer, (3) a pharmaceutically acceptable excipient, and (4) wherein the composition is substantially sugar-free comprising into the oral cavity of an individual, classified in class 424, subclass 434.

VI. Claims 102-104, drawn to a method of treating pain comprising introducing a composition comprising (1) fentanyl or a pharmaceutically acceptable salt thereof, (2) a pharmaceutically acceptable excipient, and (3) wherein the composition is substantially sugar-free comprising into the oral cavity of an individual, classified in class 424, subclass 434.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions as claimed can be used in a materially different manner. The compositions as claimed can be used in a method for treating pain wherein the

compositions are introduced into the oral cavity of a individual. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

3. Inventions I-II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions as claimed can be used in a materially different manner. The compositions as claimed can be used in a method for treating pain wherein the compositions are introduced into the oral cavity of a individual. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

4. Inventions I-II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions as claimed can be used in a materially different manner. The compositions as claimed can be used in a method for the oral transmucosal delivery

wherein said compositions are delivered to an individual via the oral mucosa. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

5. Inventions I-II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions as claimed can be used in a materially different manner. The compositions as claimed can be used in a method for the oral transmucosal delivery wherein said compositions are delivered to an individual via the oral mucosa. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

6. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, effects, and functions. Specifically, Invention I is drawn to a composition comprising (1) an ionizable pharmaceutical agent, (2) a buffer, (3) a pharmaceutically acceptable excipient, and (4) wherein the composition is substantially sugar-free, whereas Invention II is drawn to a

composition comprising (1) fentanyl or a pharmaceutically acceptable salt thereof, (2) a pharmaceutically acceptable excipient, and (3) wherein the composition is substantially sugar-free. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

7. Inventions III-IV and Inventions V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, effects, and functions. Specifically, Inventions III-IV are drawn to a method for the oral transmucosal delivery of a composition, whereas Inventions V-VI are drawn to a drawn to a method of treating pain. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

8. Searching the inventions of Groups I – VI together would impose a search burden on the examiner. In the instant case, the search of two materially distinct compositions and methods of using said compositions would impose a search burden on the examiner.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and the search required for each subset of Groups I – VI are not required for one another, restriction for examination purposes as indicated is proper.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. **In the event that applicant elects Group I or II the following election of species is required.** This application contains claims directed to the following patentably distinct species of pharmaceutically acceptable excipients:

Applicant is required to select a single pharmaceutically acceptable excipient or pharmaceutically acceptable excipient combination chosen from the instant claims 2-14, 27-29 and 47-58, 69-71, 85.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. **In the event that applicant elects Group I or II the following election of species is required.** This application contains claims directed to the following patentably distinct species of polyhedric alcohol and binding agent combinations:

Applicant is required to select a polyhedric alcohol and binding agent combination chosen from the instant claims 15-18, and 59-62, 72-75, 86-87.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. **In the event that applicant elects Group I or II the following election of species is required.** This application contains claims directed to the following patentably distinct species of buffer combinations:

Applicant is required to select a buffer combination chosen from the instant claims 30-31, and 67-68, 90.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. **In the event that applicant elects Group II the following election of species is required.** This application contains claims directed to the following patentably distinct species of a pharmaceutical agent:

Applicant is required to select either one of the following patentably distinct pharmaceutical agents:

(a) fentanyl,

(b) fentanyl citrate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 44 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

18. **In the event that applicant elects Group I or II the following election of species is required.** This application contains claims directed to the following patentably distinct species of a dosage forms

Applicant is required to select either one of the following patentably distinct dosage forms:

(a) compressed powder form,

(b) hard candy form.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 44 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

19. Applicant's agent, Scott Larsen, was contacted on 12/28/2005 concerning this election requirement. Mr. Larsen was informed that, due to the complexity of the action, the action was submitted in writing.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615

12/28/05

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PRIMARY EXAMINER
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